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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/457,931 | 12/08/1999 | H. RALPH SNODGRASS | 441472000100 | 8228 |

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EXAMINER

CHEN, SHIN LIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 02/27/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/457,931

Applicant(s)

SNODGRASS, H. RALPH

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 19, 20 and 34-41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 10-18 is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 and 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 18.
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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DETAILED ACTION

It should be noted that examiner for the present application has been changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen.

Applicant's amendment filed 12-18-01 has been entered. Claims 1, 2, 8 and 21-23 have been amended. Claims 1-41 are pending. Claims 1-18 and 21-33 are under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amendment filed 12-18-01 necessitates this new ground of rejection.

The phrase "unmodified mammalian embryoid body" in claim 1 line 3 is vague and renders the claim indefinite. It is unclear as to the metes and bounds of what would be considered "unmodified embryoid body". The specification fails to define what "unmodified embryoid body" is. It is unclear as not to be affected by what factor is "unmodified". Claims 3-9 depend on claim 1 but fail to clarify the indefiniteness.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term “unmodified” in claim 1 of the amendment filed 12-18-01 is considered a new matter because the specification fails to provide support for “unmodified embryoid body”. The specification fails to define “unmodified embryoid body” and fails to teach the use of “unmodified embryoid body” in the claimed method of creating a molecular profile of a chemical composition suspected of toxicity.

5. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24 is directed to the method of claim 21, 22, or 23, wherein the test chemical composition is known or unknown. The claim encompasses **unknown** test chemical composition. Since the test chemical composition is **unknown**, one skilled in the art at the time

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of the invention would not know the presence of said unknown test composition. Further, the specification fails to describe the unknown test composition and fails to reasonably convey to one skilled in the art that applicants were in possession of the unknown test composition. Thus it is concluded that the written description requirement is not satisfied for the unknown test composition.

6. Claims 21-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 21-33 are directed to a method of typing toxicity of a test chemical composition by comparing the molecular profiles of gene or protein expression in an isolated mammalian embryoid body (EB) with or without the treatment of said test chemical composition, and a method of typing toxicity or ranking toxicity of a test chemical composition by comparing the molecular profiles of gene or protein expression in an isolated mammalian embryoid body (EB) having the treatment of said test chemical composition with a composite library of molecular profiles of chemical compositions having predetermined toxicities. Claim 24 specifies the chemical composition is known or unknown. Claims 26-28 and 31-33 specify the chemical composition having predetermined toxicities are therapeutic agents, neurotoxins, renal toxins, hepatic toxins, myotoxins, agents that are toxic to cells of one or more reproductive organs,

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teratogenic agents, carcinogens, agricultural chemicals, cosmetics, or environmental contaminants.

Claim 24 read on typing or ranking toxicity of a test chemical composition that is unknown. As discussed in the written description rejection set forth above, the specification fails to reasonably convey to one skilled in the art that applicants were in possession of the unknown test chemical composition. Since applicants does not have possession of the unknown test chemical composition, one skilled in the art at the time of the invention would not know how to type or rank the toxicity of the unknown test chemical composition by using the claimed methods.

With regard to the claimed method of typing or ranking toxicity of a test chemical composition, the specification fails to provide adequate guidance and evidence for how one type or rank the toxicity of a chemical composition by comparing the molecular profiles of gene or protein expression of said chemical composition with molecular profile of a control or with a composite library of molecular profiles of chemical compositions having predetermined toxicities. The molecular profile of gene or protein expression of a chemical composition encompasses numerous up- or down-regulated gene or protein expressions, and different chemical compositions could result in very different and irregular molecular profile of gene or protein expressions. It is unclear how one determines certain type of up- or down-regulated gene or protein expression is indicative of toxicity or ranking of toxicity of the test chemical composition and another type of up- or down-regulated gene or protein expression is indicative

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of non-toxicity of the test chemical composition. The specification fails to provide correlation between the pattern of gene or protein expression in a mammalian EB treating with a chemical composition and the toxicity of said chemical composition. In the absence of the correlation set forth above, one skilled in the art at the time of the invention would not know how to type or rank the toxicity of a chemical composition by comparing the molecular profiles of gene or protein expression in an isolated mammalian EB having the treatment of said chemical composition with the molecular profile of a control or with a composite library of molecular profiles of chemical compositions having predetermined toxicities. Thus, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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8. Claims 1, 3-5 and 7 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wobus et al. (US Patent No. 6,007,993, 1999, effective filing date of 2-24-98). Applicant's arguments filed 12-18-01 have been fully considered but they are not persuasive.

Applicant amended claim 1 to recite "unmodified embryoid body" and argues that Wobus uses transgenic embryonic stem cell clones. This is not found persuasive because, as discussed above, the phrase "unmodified embryoid body" is considered new matter. The specification fails to define what would be considered "unmodified embryoid body". Further, the embryoid body used by Wobus is considered unmodified before treating said embryoid body with chemical agents, such as retinoic acid (RA). Thus, claims 1, 3-5 and 7 remain rejected under 35 U.S.C. 102(e).

Conclusion

Claims 1, 3-9 and 21-33 are rejected. Claims 2 and 10-18 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

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Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in cursive script, appearing to read 'S. Chen'.